Docket No. 216226US 25 CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

FULTON III, ET AL.

GAU: 3736 (Anticipated)

SERIAL NO: New Application
(Continuation of serial No. 09/900,801)

EXAMINER: B. Szmal (Anticipated)

FILED: Herewith

FOR: BIOPSY LOCALIZATION METHOD
AND DEVICE

37 CFR 1.607(a) AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

IN THE SPECIFICATION

Page 1, cancel the paragraph at lines 4-9 and substitute the following.

This application is a continuation of application serial No. 09/900,801 filed July 6, 2001, which is a continuation of application serial No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, application No. 60/117,421, filed January 27, 1999.

IN THE CLAIMS

Please cancel claim 1-52.

Please add claims 53-89 as follows:

53. A method for marking a site within the body of a mammalian patient from which a tissue sample has been removed, said method comprising the step of:

A. introducing into the site a detectable marker that (i) remains present at the site in sufficient quantity to permit detection and location of the site for at least a predetermined first time period after introduction and (ii) does not interfere with imaging of tissue adjacent the site at a predetermined second time point after introduction.

54. The method of claim 53 wherein the detectable marker is imageable, and wherein the marker remains present at the site in sufficient quantity to allow detection of the site by imaging of the marker at said first time point but clears sufficiently from the site so as to not interfere with imaging of tissue adjacent the site at said second time point.

55. The method of claim 54 wherein the imaging method by which the detectable marker is detected is selected from the group of imaging methods consisting of:

X-ray;

fluoroscopy;

mammography;

computed tomography;

magnetic resonance imaging;

ultrasound;

Doppler,

radiation detector; and

possible combinations thereof.

56. The method of claim 53 wherein the marker is detectable by palpation.

57. The method of claim 56 wherein the palpable marker is selected from the group consisting of:

at least one bead;

a flowable space occupying material;

a collagenous material;

a gelatinous material;

gelatin;

cross-linked gelatin; and

possible combinations thereof.

58. The method of claim 53 wherein the marker is visually detectable.

59. The method of claim 58 wherein the visually detectable marker is a colored substance selected from the group consisting of:

a dye;

a coloring agent;

carbon; and

possible combinations thereof.

60. The method of claim 53 wherein the detectable marker is detectable by a detection method selected from the group consisting of:

imaging of the marker;

palpation of the marker;

visualization of the marker; and

possible combinations thereof.

61. The method of claim 53 wherein the detectable marker introduced in Step A comprises:

a detectable material that will interfere with imaging of tissues adjacent thereto and which remains present at the site in sufficient quantity to permit location of the site by imaging until the first time point but clears sufficiently from the site to not interfere with imaging of tissue adjacent the site at said second time point.

62. The method of claim 53 wherein the detectable marker introduced in Step A comprises:

a quantity of detectable material that, if introduced into the site alone, would clear from the site such that a detectable quantity of the marker would no longer be present at the site at 2 weeks after introduction of said detectable marker; and,

a clearance delaying element that delays the clearance of said material from the site such that (i) a detectable quantity of said material remains present at the site until at least said first time point and (ii) said material clears sufficiently from the site to permit imaging of tissue adjacent to the site without interference from said detectable marker at said second time point.

63. The method of claim 62 wherein the detectable material is a lipid.

64. The method of claim 62 wherein the clearance delaying element is selected from the group consisting of:

polylactic acid;

polyglycolic acid;

an encapsulating material;

collagen;

renatured collagen;

gelatin;

renatured gelatin;

crosslinked gelatin; and

the possible combinations thereof.

65. The method of claim 53 wherein the detectable marker comprises a material that is detectable by radiographic imaging means.

66. The method of claim 53 wherein the detectable marker comprises a material that is detectable by sonographic imaging means.

67. The method of claim 53 wherein the detectable marker comprises a material that is detectable by magnetic imaging means.

68. The method of claim 53 wherein the detectable marker comprises a dry powder.

69. The method of claim 53 wherein the detectable marker comprises a sponge.

70. The method of claim 53 wherein the detectable marker comprises a liquid.

71. The method of claim 53 wherein the detectable marker comprises a flowable material.

72. The method of claim 53 wherein the detectable marker comprises a collagenous material having radiographically imageable matter attached thereto.

73. The method of claim 72 wherein the collagenous material of the marker comprises renatured collagen.

74. The method of claim 73 wherein the collagenous material is also covalently crosslinked.

75. The method of claim 72 wherein the radiographically imageable matter comprises ions.

76. The method of claim 74 wherein the radiographically imageable matter comprises a radiopaque marker.

77. The method of claim 72 wherein the collagenous material of the marker comprises renatured collagen and the radiographically imageable matter of the marker comprises ions that are bound to said renatured collagen.

78. A method according to claim 75 wherein the marker is prepared by a process that comprises:

a. obtaining a quantity of denatured collagenous material;

b. renaturing the collagenous material; and,

c. binding ions to the renatured collagenous material.

79. A method according to claim 76 wherein the marker is prepared by a process that comprises:

a. obtaining a quantity of denatured collagenous material;

b. renaturing the collagenous material; and

c. dispersing a radiopaque marker throughout the renatured collagenous material.

80. The method of claim 72 wherein the decectable marker comprises a gelatinous material having radiographically imageable matter combined therewith.

81. The method of claim 80 wherein the gelatinous material of the marker comprises renatured gelatin.

82. The method of claim 81 wherein the gelatinous material is also covalently crosslinked.

83. The method of claim 80 wherein the radiographically imageable matter comprises ions.

84. The method of claim 80 wherein the radiographically imageable matter comprises a radiopaque marker.

85. The method of claim 80 wherein the gelatinous material of the marker comprises renatured gelatin and the radiographically imageable matter of the marker comprises ions that are bound to said renatured gelatin.

86. The method of claim 75 wherein the marker is prepared by a process that comprises:

d. obtaining a quantity of denatured gelatin;

e. renaturing the gelatin; and,

f. binding ions to the renatured gelatin.

87. The method of claim 76 wherein the marker is prepared by a process that comprises:

d. obtaining a quantity of denatured gelatin;

e. renaturing the gelatin; and,

f. dispersing a radiopaque marker throughout the renatured gelatin.

88. A method of identifying tissue that is located within a predetermined distance of a boundary of a biopsy cavity that has been created by the removal of a biopsy specimen from a patient, said method comprising the steps of:

a. introducing into the biopsy cavity a quantity of marker material that is visibly distinguishable from blood and surrounding tissue so as to delineate the outer boundaries of the biopsy cavity;

b. forming an incision in the patient to permit visualization of the marker material and the boundaries of the biopsy cavity delineated thereby; and,

c. identifying the tissue that lies within said predetermined distance of the boundary of the biopsy cavity.

89. The method of claim 88 wherein it is desired to remove the tissue that lies within said predetermined distance of a boundary of the biopsy cavity and wherein the method further comprises the step of:

d) excising and removing tissue that lies within said predetermined distance of the boundary of the biopsy cavity.

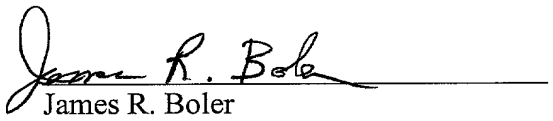
REMARKS

Claims 53-89 are present in the application.

Claims 1-52 have been canceled.

Claims 53-89 have been presented to provoke an interference with U.S. patent No. 6,161,034 as stated in applicants' 37 CFR 1.607 request submitted concurrently herewith.

Respectfully submitted,



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APPENDIX

The following is a marked up copy of the amended paragraph at lines 4-9 from page 1 of the specification.

This application is a continuation of application serial No. 09/900,801 filed July 6, 2001, which is a continuation of application serial No. 09/366,360 filed June 18, 1999, which application claims the benefit of the following Provisional parent applications. Biopsy Localization Device, application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, application No. 60/117,421, filed January [25] 27, 1999.